

Remarks

Reconsideration and withdrawal of the rejections set forth in the Office action dated March 31, 2006 are respectfully requested.

I. Amendments

Claims 7-11 are canceled.

Claim 1 is amended to recite an pharmaceutically effective amount of an extract being capable of preventing induction or metastasis of lung cancer and large intestine cancer caused by a carcinogen. Basis for this amendment can be found, for example, in Examples 2, 4, and 8.

Claims 3-5 are amended for clarity.

No new matter is added by way of these amendments.

II. Rejection under 35 U.S.C. §101

Claim 11 was rejected under 35 U.S.C. §101 as allegedly directed to non-statutory matter. Claim 11 stands canceled. Accordingly, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §101.

III. Rejection under 35 U.S.C. §112, first paragraph

Claims 1-11 were rejected under 35 U.S.C. §112, first paragraph, allegedly because the specification does not enable any person skilled in the art to which it pertains, or with which it is most connected to make and use the invention commensurate in scope with the claims.

These rejections are respectfully traversed.

The first paragraph of 35 U.S.C. §112 requires that the specification of a patent enable any person skilled in the art to which it pertains to make and use the claimed invention without undue experimentation (e.g., *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir., 1991).

The Examiner states that the specification is enabled for "a composition for inhibition or treatment of metastasis and cancer" (page 2 of Office action mailed

March 31, 2006). Further, Example 1 provides guidance for an exemplary method of preparation of an agaricus extract (page 15, line 15, through page 17, line 12). Examples 2-3, for example, provide guidance for administering the extract to inhibit induction or metastasis of lung cancer. Example 8, for example, provides guidance for administering the extract to inhibit induction or metastasis of large intestine cancer.

Accordingly, Applicants submit that the specification would enable any person skilled in the art to which it pertains to make and use the claimed invention.

In light of the above, Applicants submit that the present claims satisfy the requirements of 35 U.S.C. § 112, first paragraph and respectfully request that the rejections be withdrawn.

IV. Rejection under 35 U.S.C. § 112, second paragraph

Claims 3-5 and 11 were rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The Examiner had five specific objections which are set forth and discussed below.

Claim 11 is canceled. The objections to the remaining claims are addressed below.

1. Rejection of claims 3-5

The language "hot" was objected to as allegedly unclear. Applicants' amendment obviates this objection.

2. Rejection of claim 4

The language "main elute fraction" was objected to as allegedly unclear what temperatures are encompassed. Applicants' amendment obviates this objection.

In view of the above, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

V. Rejection under 35 C.F.R. §102

Claims 1-11 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Tomihisa *et al.* (JP Publication No. 2001-010970). These rejections are respectfully traversed.

A. The Present Claims

The present claims relate to a pharmacologically effective amount of an extract from agaricus. The extract is capable of preventing induction or metastasis of lung cancer and large intestine cancer caused by a carcinogen.

B. The Prior Art

TOMIHISA ET AL. describe a composition extracted from Agaricus blazei Murill that is administered to a mouse transplanted with Sarcoma 180 cells.

C. Analysis

According to the M.P.E.P. § 2131, “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference”.

Tomihisa *et al.* fail to teach a pharmacologically effective amount of an extract from agaricus being capable of preventing induction or metastasis of lung cancer and large intestine cancer caused by a carcinogen. Instead, Tomihisa *et al.* teach administering a composition extracted from agaricus to a mouse transplanted with Sarcoma 180.

Accordingly, Applicants submit that the standard of strict identity to maintain a rejection under 35 U.S.C. § 102 has not been met. Withdrawal of the rejections under 35 U.S.C. § 102 is respectfully requested.

VI. Rejections under 35 U.S.C. §103

Claims 9 and 10 were rejected under 35 U.S.C. §103 as allegedly obvious over Tomihisa *et al.*

These rejections are respectfully traversed.

A. The Present Claims are described above.

B. The Cited Reference

TOMIHISA ET AL is described above.

C. Analysis

According to the M.P.E.P. § 2143, one of the three basic criteria that must be met to establish a prima facie case of obviousness is that the prior art references (or references when combined) must teach or suggest all the claim limitations.

The deficiencies of Tomihisa *et al.* are discussed above. One skilled in the art would not understand the composition of Tomihisa *et al.* to be a pharmaceutically effective amount of an extract that is effective in the treatment of lung cancer and large intestine cancer caused by a carcinogen. Nor would one skilled in the art be motivated to modify the composition of the Tomihisa *et al.* to a pharmaceutically effective amount of an extract from agaricus where the extract is capable of preventing induction or metastasis of lung cancer and large intestine cancer caused by a carcinogen. There is simply no guidance to do so. Further, Sarcoma 180 (as described in Tomihisa *et al.*) and lung cancer and large intestine cancer caused by a carcinogen (as in the present claims) have different clinical and microscopic characteristics and are generally treated differently.

Because the references fail to teach all the claim limitations of the present invention, the standard for obviousness has not been met. Accordingly, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §103.

VII. Conclusion

In view of the foregoing, Applicants submit that the claims pending in the application are in condition for allowance. A Notice of Allowance is therefore respectfully requested.

The Examiner is invited to contact Applicants' representative at (650) 838-4410 if it is believed that prosecution of this application may be assisted thereby.

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